

a material issue, and must include a recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the Regional Food and Drug Director must render a decision on the appeal affirming or revoking the detention order within 5-working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the Regional Food and Drug Director finds that the shell eggs were produced or held in violation of this section, he must affirm the order that they be diverted, under the supervision of an officer or employee of FDA for processing under the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the Regional Food and Drug Director must issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order, he must order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision must be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director constitutes final agency action, subject to judicial review.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or, if applicable, the State or local representative may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(b) *Inspection.* Persons engaged in production of shell eggs must permit authorized representatives of FDA to

make, at any reasonable time, an inspection of the egg production establishment in which shell eggs are being produced. Such inspection includes the inspection and sampling of shell eggs and the environment, the equipment related to production of shell eggs, the equipment in which shell eggs are held, and examination and copying of any records relating to such equipment or eggs, as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(c) *State and local cooperation.* Under sections 311 and 361 of the Public Health Service Act, any State or locality that is willing and able to assist the agency in the enforcement of §§118.4 through 118.10, and is authorized to inspect or regulate egg production establishments, may, in its own jurisdiction, enforce §§118.4 through 118.10 through inspections under paragraph (b) of this section and through administrative enforcement remedies specified in paragraph (a) of this section unless FDA notifies the State or locality in writing that such assistance is no longer needed. A state or locality may substitute, where necessary, appropriate State or local officials for designated FDA officials in this section. When providing assistance under paragraph (a) of this section, a State or locality may follow the hearing procedures set out in paragraphs (a)(2)(iii) through (a)(2)(v) of this section, or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

(d) *Preemption.* No State or local governing entity shall establish, or continue in effect any law, rule, regulation, or other requirement regarding prevention of SE in shell eggs during production, storage, or transportation that is less stringent than those required by this part.

PART 119—DIETARY SUPPLEMENTS THAT PRESENT A SIGNIFICANT OR UNREASONABLE RISK

AUTHORITY: 21 U.S.C. 321, 342, 343, 371.

§ 119.1 Dietary supplements containing ephedrine alkaloids.

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

[69 FR 6853, Feb. 11, 2004]

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

- Sec.
- 120.1 Applicability.
- 120.3 Definitions.
- 120.5 Current good manufacturing practice.
- 120.6 Sanitation standard operating procedures.
- 120.7 Hazard analysis.
- 120.8 Hazard Analysis and Critical Control Point (HACCP) plan.
- 120.9 Legal basis.
- 120.10 Corrective actions.
- 120.11 Verification and validation.
- 120.12 Records.
- 120.13 Training.
- 120.14 Application of requirements to imported products.

Subpart B—Pathogen Reduction

- 120.20 General.
- 120.24 Process controls.
- 120.25 Process verification for certain processors.

AUTHORITY: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 2421, 264.

SOURCE: 66 FR 6197, Jan. 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible por-

tions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than \$500,000, or if their total annual sales are greater than \$500,000 but their total food sales are less than \$50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.

§ 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and part 110 of this chapter are applicable to such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.

(b) *Control* means to prevent, eliminate, or reduce.

(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.